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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 9

### Complete if Known

Application Number	10/551,203
Filing Date	June 29, 2006
First named Inventor	Simon West
Group Art Unit	1612
Examiner name	Snigdha Maewall
Attorney Docket Number	024944-9015-US00

### U.S. Patent Documents

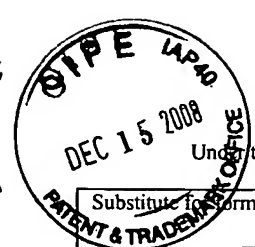
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	2,407,823	Fieser	9/17/1946
	2,913,477	Hirschmann	11/17/1959
	3,212,901	Robeson	10/19/1965
	4,075,333	Josse	2/21/1978
	4,141,938	Klose	2/27/1979
	4,299,906	Liu	11/10/1981
	4,654,373	Bertelli	3/31/1987
	4,684,520	Bertelli	8/4/1987
	4,686,211	Hara et al.	8/11/1987
	4,874,883	Uphues et al.	10/17/1989
	4,952,495	Belly et al.	8/28/1990
	5,041,434	Lubkin	8/20/1991
	5,053,222	Takasu et al.	10/1/1991
	5,091,848	Kojima	2/25/1992
	5,094,848	Brixner	3/10/1992
	5,114,957	Hendler et al.	5/19/1992
	5,138,084	Casagrande et al.	8/11/1992
	5,173,304	Lohner et al.	12/22/1992
	5,374,645	Kurihara-Bergstrom et al.	12/20/1994
	5,387,579	Meybeck et al.	2/7/1995
	5,446,070	Mantelle	8/29/1995
	5,474,891	Murphy	12/12/1995

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Sheet 2 of 9

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**U.S. Patent Documents**

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
	5,474,991	Ogata et al.	12/12/1995
	5,554,781	Reierson	9/10/1996
	5,570,504	Distefano et al.	11/5/1996
	5,583,105	Kovacs et al.	12/10/1996
	5,589,504	Dannenberg et al.	12/31/1996
	5,603,949	Meybeck et al.	2/18/1997
	5,607,921	Bernard et al.	3/4/1997
	5,643,597	Meybeck et al.	7/1/1997
	5,741,518	Ribier et al.	4/21/1998
	5,759,526	Simonnet et al.	6/2/1998
	5,776,915	Peterson et al.	7/7/1998
	5,780,504	Ptchelintsev	7/14/1998
	5,804,168	Murad	9/8/1998
	5,804,216	Terren et al.	9/8/1998
	5,807,542	Challis et al.	9/15/1998
	5,807,845	Ogata et al.	9/15/1998
	5,885,595	Corey et al.	3/23/1999
	5,906,811	Hersh	5/25/1999
	5,908,846	Bundgaard et al.	6/1/1999
	5,916,915	Hong Jong Eon et al.	6/29/1999
	5,928,631	Lucas et al.	7/27/1999
	5,965,750	Oonishi et al.	10/12/1999

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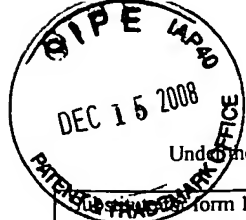
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	5,981,474	Manning et al.	11/9/1999
	6,022,867	Ito et al.	2/8/2000
	6,046,181	Oonishi et al.	4/4/2000
	6,048,891	Wechter	4/11/2000
	6,096,326	Wikholm	8/1/2000
	6,121,249	Weissman et al.	9/19/2000
	6,184,247	Schneider	2/6/2001
	6,403,811	West	6/11/2002
	6,417,223	Sanders et al.	7/9/2002
	6,423,742	Larson	7/23/2002
	6,444,220	Wiley	9/3/2002
	6,479,540	Constantinides et al.	11/12/2002
	6,579,995	West	6/17/2003
	6,599,933	Takada et al.	7/29/2003
	6,645,998	Sanders et al.	11/11/2003
	6,703,384	Sanders et al.	3/9/2004
	6,770,672	Sanders et al.	8/3/2004
	7,179,486	Mulye	2/20/2007
	2002/0131994	Schur et al.	9/19/2002
	2002/0151467	Leung	10/17/2002
	2003/0035812	Ito et al.	2/20/2003
	2003/0206972	Babish et al.	11/6/2003

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Sheet 4 of 9

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Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
		2004/0052754	West et al.	3/18/2004
		2004/0096493	West	5/20/2004
		2004/0097431	Sanders et al.	5/20/2004
		2004/0097472	West et al.	5/20/2004
		2004/0204343	Fishman	10/14/2004
		2004/0235938	Sanders et al.	11/25/2004
		2004/0241225	West	12/2/2004
		2005/0009787	West et al.	1/13/2005
		2005/0089495	West	4/28/2005
		2006/0241085	West et al.	10/26/2006
		2006/0257459	West et al.	11/16/2006
		2006/0281715	West	12/14/2006
		2007/0042999	West et al.	2/22/2007
		2007/0135390	West et al.	6/14/2007

**FOREIGN PATENT DOCUMENTS**

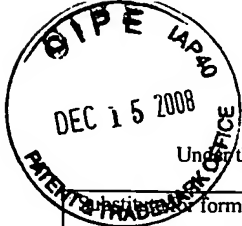
Examiner Initials		Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
		CA	1337992	Shiseido Co. Ltd. et al.	1/23/1996		X
		EP	0171009	Henkel Corporation	2/12/1986		X
		EP	0324387	Takeda Chemical Industries Ltd.	7/19/1989		X
		EP	0338429	BASF AG	10/25/1989		

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Sheet 5 of 9

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First named Inventor	Simon West
Group Art Unit	1612
Examiner name	Snigdha Maewall
Attorney Docket Number	024944-9015-US00

**U.S. Patent Documents****FOREIGN PATENT DOCUMENTS**

Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
	EP	0430045	Senju Pharmaceutical Co., Inc.	6/5/1991		X
	EP	0430336	Zambon Group SpA	6/5/1991		X
	EP	0436911	Eisai Co., Ltd.	7/17/1991		X
	EP	0565007	Senju Pharmaceutical Co., Inc.	10/13/1993		X
	EP	0574255	Indena SpA	12/15/1993		X
	EP	0617963	Senju Pharmaceutical Co., Inc.	10/5/1994		X
	EP	0641790	Scotia Holdings Plc	3/8/1995		X
	EP	0661053	Senju Pharmaceutical Co., Inc.	7/5/1995		X
	EP	0679399	Senju Pharmaceutical Co., Inc.	11/2/1995		X
	EP	0680760	Senju Pharmaceutical Co., Inc.	11/8/1995		X
	EP	0684043	Senju Pharmaceutical Co., Inc.	12/29/1995		X
	EP	0699440	Senju Pharmaceutical Co., Inc.	3/6/1996		X
	EP	0826365	Senju Pharmaceutical Co., Inc.	3/4/1998		X
	EP	0845216	Showa Denko Kabushiki Kaisha	6/3/1998		X
	EP	0965328	Kao Corporation	12/22/1999		X
	EP	1023897	Showa Denko KK	8/2/2000		X
	EP	1053749	Senju Pharmaceutical Co., Inc.	11/22/2000		X
	GB	1121683	General Aniline & Film Corporation	7/31/1968		X
	GB	2227662	E.R. Squibb & Sons Inc.	8/8/1990		X
	JP	53015381	Eisai Co. Ltd.	2/13/1978		X
	JP	58180410	Shiseido Co. Ltd. et al.	10/21/1983		X
	JP	59044375	Senju Seiyaku KK	3/12/1984		X

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary) Sheet 6 of 9	<b>Complete if Known</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">Application Number</td> <td>10/551,203</td> </tr> <tr> <td>Filing Date</td> <td>June 29, 2006</td> </tr> <tr> <td>First named Inventor</td> <td>Simon West</td> </tr> <tr> <td>Group Art Unit</td> <td>1612</td> </tr> <tr> <td>Examiner name</td> <td>Snigdha Maewall</td> </tr> <tr> <td>Attorney Docket Number</td> <td>024944-9015-US00</td> </tr> </table>	Application Number	10/551,203	Filing Date	June 29, 2006	First named Inventor	Simon West	Group Art Unit	1612	Examiner name	Snigdha Maewall	Attorney Docket Number	024944-9015-US00
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U.S. Patent Documents

**FOREIGN PATENT DOCUMENTS**

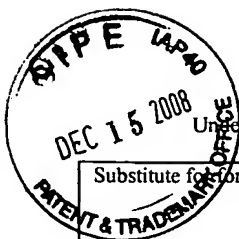
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	JP	59157091	Sanyo Chem. Ind. Ltd.	9/6/1984		X
	JP	61086940	Kao Corporation	5/2/1986		X
	JP	61091137	Kao Corporation	5/9/1986		X
	JP	61233631	Kao Corporation	10/17/1986		X
	JP	62195393	Yakult Honsha KK	8/28/1987		X
	JP	63139972	Senju Pharmaceutical Co., Inc.	6/11/1988		X
	JP	4208209	Showa Denko KK	7/29/1992		X
	JP	5132700	Sunstar Chemical Industries	5/28/1993		X
	JP	6048962	Morimoto Kazutoshi	2/22/1994		X
	JP	6078214	Senju Pharmaceutical Co., Inc.	10/5/1994		X
	JP	7011291	Kao Corporation	1/13/1995		X
	JP	7278587	Kao Corporation	10/24/1995		X
	JP	7316170	Kao Corporation	12/5/1995		X
	JP	8193089	Kao Corporation	7/30/1996		X
	JP	8311085	Kao Corporation	11/26/1996		X
	JP	9044375	Hitachi Ltd.	2/14/1997		X
	JP	9309813	Nonogawa Shoji KK	12/2/1997		X
	JP	10045783	Showa Denko KK	2/17/1998		X
	JP	11043436	Showa Denko KK	2/16/1999		X
	JP	11199424	Nonogawa Shoji KK	7/27/1999		X
	JP	11199465	Nonogawa Shoji KK	7/27/1999	X	X
	JP	2001247585	Nippon Oils & Fats Co. Ltd.	9/11/2001		X
	JP	2002080475	Takada Jiro	3/19/2002		X

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	Application Number	10/551,203
	Filing Date	June 29, 2006
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## U.S. Patent Documents

## FOREIGN PATENT DOCUMENTS

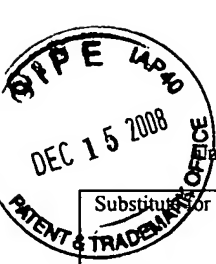
Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
	SU	925961	MO I T Pishchevoj Promy	5/7/1982		X
	WO	91/17987	SmithKline & French Laboratories Ltd.	11/28/1991		X
	WO	92/03122	CEVC	3/5/1992		X
	WO	92/07544	Senju Pharmaceutical Co., Inc.	5/14/1992		X
	WO	92/08459	Kabi Pharmacia AB	5/29/1992		X
	WO	93/02661	LVMH Rech	2/18/1993		X
	WO	93/15731	Lamb	8/19/1993		X
	WO	93/24131	Procter & Gamble Pharmaceuticals Inc.	12/9/1993		X
	WO	95/31217	A/S Dumex	11/23/1995		X
	WO	95/34303	Arcturus Pharmaceutical Corp.	12/21/1995		X
	WO	96/17852	Kao Corporation	6/13/1996		X
	WO	96/20715	Perstorp AB	7/11/1996		X
	WO	96/21440	Alpha-Therapeutics Inc. et al.	7/11/1996		X
	WO	96/29336	Medical Research Council et al.	9/26/1996		X
	WO	97/14705	Showa Denko KK	4/24/1997		X
	WO	97/35591	Inspire Pharmaceuticals Inc.	10/2/1997		X
	WO	99/58555	Vyrex Corporation	11/18/1999		X
	WO	00/08033	The University of Kansas	2/17/2000		X
	WO	00/16772	Research Development Foundation	3/30/2000		X
	WO	00/30620	Gasco	6/2/2000		X
	WO	00/43380	Swig Pty. Ltd.	7/27/2000		X

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Sheet 8 of 9

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	WO	00/57876	Lipogenics, Inc.	10/5/2000		X
	WO	00/59475	Lipocine Inc.	10/12/2000		X
	WO	00/69865	Swig Pty. Ltd.	11/23/2000		X
	WO	00/71094	Amway Corporation	11/30/2000		X
	WO	00/71125	LTS Lohmann Therapie- Systeme AG	11/30/2000		X
	WO	01/19372	Pharmacia & Up John SpA	3/22/2001		X
	WO	01/22937	Sonus Pharmaceuticals, Inc.	4/5/2001		X
	WO	01/35998	Pharmaderm Laboratories, Ltd.	5/25/2001		X
	WO	01/46204	Merck Frosst Canada & Co.	6/28/2001		X
	WO	01/58889	Research Development Foundation	8/16/2001		X
	WO	02/13810	Vyrex Corporation	2/21/2002		X
	WO	02/26238	Tocovite Pty Ltd.	4/4/2002		X
	WO	02/36736	The Regents of University of California	5/10/2002		X
	WO	02/39996	Pharmacia & Up John Company	5/23/2002		X
	WO	03/011303	Vital Health Sciences Pty. Ltd.	2/13/2003		X
	WO	03/039461	Research Development Foundation	5/15/2003		X
	WO	03/043570	Galileo Laboratories Inc.	5/30/2003		X
	WO	03/049774	Vital Health Sciences Pty. Ltd.	6/19/2003		X
	WO	03/053407	Research Development Foundation	7/3/2003		X
	WO	03/101480	Perricone	12/11/2003		X

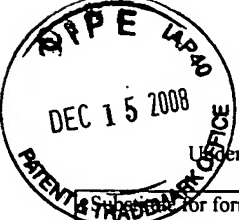
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	WO	2004/060315	Perricone	7/22/2004		X	
	WO	2004/064831	Vital Health Sciences Pty. Ltd.	8/5/2004		X	
	WO	2004/092186	Vital Health Sciences Pty. Ltd.	10/28/2004		X	
	WO	2004/092187	Vital Health Sciences Pty. Ltd.	10/28/2004		X	
	WO	2005/023282	LTT Bio-Pharma Co. Ltd.	3/17/2005		X	
	WO	2005/084678	Vital Health Sciences Pty. Ltd.	9/15/2005		X	
	WO	2006/012692	Vital Health Sciences Pty. Ltd.	2/9/2006		X	
	WO	2006/092024	Vital Health Sciences Pty. Ltd.	9/8/2006		X	
	WO	2006/092025	Vital Health Sciences Pty. Ltd.	9/8/2006		X	
	WO	2006/133506	Vital Health Sciences Pty. Ltd.	12/21/2006		X	
	WO	2007/070981	Vital Health Sciences Pty. Ltd.	6/28/2007		X	

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				Group Art Unit	1612
				Examiner Name	Snigdha Maewall
Sheet	1	of	6	Attorney Docket Number	024944-9015-US00

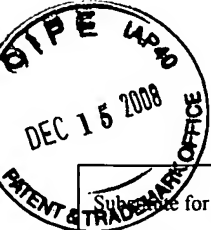
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		ABERG, F. et al., "Distribution and redox state of ubiquinones in rat and human tissues," Arch. Biochem. Biophys. (1992) 295(2):230-234
		ALMEIDA, M.E.M. et al., "Evaluation of soybean oil deodorization distillate for Vitamin E recovery," Arq. Biol. Tecnol. (1994) 37(4):1003-1011
		BARRETT, C.W. et al., "The effect of particle size and vehicle on the percutaneous absorption of fluocinolone acetone," Brit. J. Dermatol. (1965) 77:576-578
		BIKERMAN, J.J., "Mechanical destruction of young and old foam films," J. Phys. Chem. (1952) 56:164-165
		BLOM, J.H. et al., "Reproductive success of female rainbow trout ( <i>Oncorhynchus mykiss</i> ) in response to graded dietary ascorbyl monophosphate levels," Biol. of Reproduction (1995) 52:1073-1080
		CEVC, G. "Transdermal drug delivery of insulin with ultradeformable carriers," Clin. Pharmacokinet. (2003) 42(5):461-474
		CEVC, G. et al., "Ultraflexible vesicles, transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin," Biochim. Biophys. Acta (1998) 1368:201-215
		DE WOLFE, F.A. et al., "Ligand-binding proteins: their potential for application in systems for controlled delivery and uptake of ligands," Pharmacol. Rev. (2000) 52(2):207-236
		DEVARAJ, S. et al., "Modulation of monocyte-macrophage function with alpha-tocopherol: implications for atherosclerosis," Nat. Rev. (2002) 60(1):8-14

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		DEVARAJ, S. et al., "Alpha tocopherol supplementation decreases serum C-reactive protein and monocyte interleukin-6 levels in normal volunteers and type 2 diabetic patients," Free Radic. Biol. Med. (2000) 29(8):790-792
		ERNSTER, L. et al., "Biochemical, physiological and medical aspects of ubiquinone function," Biochim. Biophys. Acta (1995) 1271:195-204
		OCTOPLUS, "Formulation Development of Poorly Soluble Drugs" (www.octoplus.nl) (1999) 2 pages (downloaded 11/2008)
		FRACALOSS, D.M. et al., "Oscars, Astronotus ocellatus, have a dietary requirement for vitamin C," J. Nutrition (1998) 128:1745-1751
		FREI, B. et al., "Ubiquinol-10 is an effective lipid-soluble antioxidant at physiological concentrations," Proc. Natl. Acad. Sci. (1990) 87:4879-4883
		GODIN, B. et al., "Ethosomes: new prospects in transdermal delivery," Crit. Rev. Thera. Drug Car. Syst. (2003) 20(1):63-102
		GOFF et al., "Prevention of cardiovascular disease in persons with Type 2 diabetes mellitus: current knowledge and rationale for the action to control cardiovascular risk in diabetes (ACCORD) trial," Am. J. Cardiol. (2007) 99(suppl):4i-20i
		GRIFFIN, E. et al., "A link between diabetes and atherosclerosis: glucose regulates expression of CD36 at the level of translation," Nature Med. (2001) 7(7):840-846
		GUO, J. et al., "Transdermal delivery of insulin in mice by using Lecithin vesicles as a carrier," Drug Del. (2000) 7:113-116

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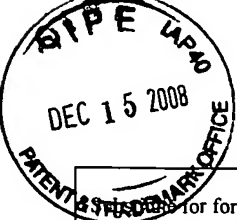
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		HERON-MILHAVET, L. et al., "Muscle-specific overexpression of CD36 reverses the insulin resistance and diabetes of MKR mice," Endocrinology (2004) 145:4667-4676
		KAGAN, V. et al., "Antioxidant effects of ubiquinones in microsomes and mitochondria are mediated by tocopherol recycling," Biochem. Biophys. Res. Commun. (1990) 169(3):851-857
		KARRER, V.P. et al., "d,l-alpha-tocopherol-phosphorsaure-ester," Zurich, Chemisches Institut der Universitat (1933) p. 1137-1138, in German
		KING, M.J. et al., "Transdermal delivery of insulin from a novel biphasic lipid system in diabetic rats," Diab. Tech. Therap. (2002) 4(4):479-488
		KNOWLER, W.C. et al., "Preventing Non-insulin-dependent diabetes," Diabetes (1995) 44:483-488
		LANGSJOEN, P.H. et al., "Overview of the use of CoQ10 in cardiovascular diseases," Biofactors (1999) 9:273-284
		LASS, A. et al., "Electron transport-linked ubiquinone-dependent recycling of $\alpha$ -tocopherol inhibits autooxidation of mitochondrial membranes," Arch. Biochem. Biophys. (1998) 352(2):229-236
		LEE, C-F. et al., "Attenuation of UV-induced apoptosis by coenzyme Q10 in human cells harboring large-scale deletion of mitochondrial DNA," Ann. N.Y. Acad. Sci. (2005) 1042:429-438
		LEI, B. et al., "Progress in alpha-tocopherol preparation technology, Xiandai Huagong (1997) 17(7):13-15

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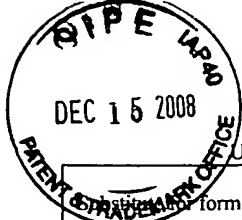
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		MAGUIRE, J.J. et al., "Succinate-ubiquinone reductase linked recycling of alpha-tocopherol in reconstituted systems and mitochondria: requirement for reduced ubiquinone," Arch. Biochem. Biophys. (1992) 292(1):47-53
		MELLORS, A. et al., "The inhibition of mitochondrial peroxidation by ubiquinone and ubiquinol," J. Biol. Chem. (1966) 241(19):4353-4356
		MERCK INDEX, THE, "α-estradiol" Thirteenth Edition, Whitehouse Station, NJ (2001) page 660
		MERCK INDEX, THE, "Fludarabine to Fludeoxyglucose F18" pages, Thirteenth Edition, Whitehouse Station, NJ (2001) pages 729-730
		MIYAMOTO, S. et al., "Synthesis of a novel phosphate ester of a vitamin E derivative and its antioxidative activity," Biosci. Biotech. Biochem. (1998) 62(12):2463-2466
		MORGAN, T.M. et al., "Transdermal delivery of estradiol in postmenopausal women with a novel topical aerosol," J. Pharm. Sci. (1998) 87(10):1226-1228
		MORGAN, T.M. et al., "Enhanced transdermal delivery of sex hormones in swine with a novel topical aerosol," J. Pharm. Sci. (1998) 87(10):1219-1225
		MORTENSEN, S.A., "Perspectives on therapy of cardiovascular diseases with coenzyme Q10 (ubiquinone)," Clin. Investig. (1993) 71(Suppl.8):S116-S123
		MUNTEANU, A. et al., "Modulation of cell proliferation and gene expression by alpha-tocopheryl phosphates: relevance to atherosclerosis and inflammation," Biochem. Biophys. Res. Comm. (2004) 318(1):311-316

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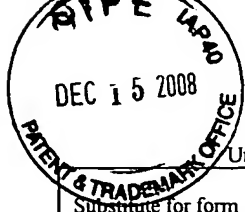
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		OWENS, D.R. et al., "Alternative routes of insulin delivery," Diabet. Med. (2003) 20:886-898
		PARKER et al., "Neonatal vitamin K administration and childhood cancer in the North of England: retrospective case-control study," BMJ (1998) 316:189-193
		POTTS, R.O. et al., "Predicting skin permeability," Pharm. Res. (1992) 9(5):663-669
		PURATCHIKODY, A. et al., "Reverse phase - high performance liquid chromatographic determination of atorvastatin calcium in solid dosage forms," Pharma. Review (2003) 1(2):79-80, 83 - STN File CA, Abstract 139:399976 only
		SEVAST'IANOV, V.I. et al., "Transdermal delivery of insulin," Meditsinskaia Tekhnika (2003) 2:21-24
		SEYAMA, Y. et al., "Comparative effects of Vitamin K2 and estradiol on experimental arteriosclerosis with diabetes mellitus," Int. J. Vitam. Nutr. Res. (2000) 70(6):301-304, Abstract only
		SINGH, R.B. et al., "Randomized double-blind placebo-controlled trial of coenzyme Q10 in patients with acute myocardial infarction," Cardio. Drugs Ther. (1998) 12:347-353
		Stedman's Medical Dictionary, "Tocopherol," "Tocotrienol," and "Vitamin K1", 22nd Edition, Williams & Wilkins Co. (1972) p. 1303 and 1400

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		YOUNIS et al., "The prevention of type 2 diabetes mellitus: recent advances," Q.J. Med. (2004) 97:451-455

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